

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 6/30/2011. Claim 22 has been canceled without prejudice, see attached interview summary where Applicant agreed to cancel claim 22 without prejudice. Claims 1-21 are pending and an action on the merits is as follows.

Applicant's arguments with respect to the newly presented limitations amended in claims 1-21 have been considered and are addressed in a new ground(s) of rejection as set forth below.

As discussed in the attached interview summary claim limitation "lancet moving mechanism for moving a lancet" has been interpreted under 35 U.S.C. 112, sixth paragraph, because it uses a non-structural term "lancet moving mechanism" coupled with functional language "moving a lancet" without reciting sufficient structure to achieve the function. Furthermore, the non-structural term is not preceded by a structural modifier.

Since this claim limitation invokes 35 U.S.C. 112, sixth paragraph, claims 1 and 21 are interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112, sixth paragraph limitation: link unit 30, moveable plate 31, lancet holder 32, pins 30a-c and

Art Unit: 3731

arms 30 A and B and associated structural and functional features of the aforementioned elements.

If applicant wishes to provide further explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may amend the claim so that it will clearly not invoke 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph.

Allowable Subject Matter

As noted in the attached interview summary if Applicant were to overcome the nonstatutory double patenting rejection as set forth below by filing a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) the claims requiring the 112 sixth paragraph invoking limitation reciting "a lancet moving mechanism for moving the lancet" would be held allowable over the prior art of record.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 3731

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/552841 (hereafter 841) in view of Kuhr et al. (US 2002/0040230).

Regarding claim 1, the 841 application discloses a lancet moving mechanism for moving the lancet as described on pages 11-13 of the instant application (note lines 4-8

Art Unit: 3731

of claim 1 of the 841 application claims the first and second members corresponding to elements 31 and 32 of the instant specification and goes on to disclose a “movement conversion means for” which is described on pages 15-17 of the 841 application including link member 30, pins 30a-c and arms 30 A and B which are also described with regard to the claimed lancet moving mechanism for moving the lancet as described on pages 11-13 of the instant application). The 841 application fails to explicitly disclose a lancet holder for retaining a lancet, the lancet including a main body and a needle projecting from the body, the lancet holder being moved in a lancing direction from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object, the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction, thus to be retained by the lancet holder, wherein the lancet holder includes a first member and a second member that are movable relative to each other, the second member being in direct contact with the first member and being movable relative to the first member between a fixing position in which the main body of the lancet is fixed to the lancet holder with a first fixing force for limiting axial removal of the lancet from the lancet holder and a non-fixing position in which the main body of the lancet is held by the lancet holder with a second fixing force smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder, the second member being moved in the lancing direction together with the first member and the lancet when the second member is held in the fixing position for fixing the lancet to the lancet holder. However, Kuhr discloses a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6)

Art Unit: 3731

projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (12a) and a second member (30) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by first member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder, the second member (capable of) being moved in the lancing direction together with the first member and the lancet when the second member is held in the fixing position for fixing the lancet to the lancet holder (note that during the loaded primed configuration, as depicted in figures 8 and 2, and during firing, portion 34 of element 30, note figures 4 and 5, is capable of moving in a puncture direction 7 within recess 43 note paragraph 36, therefore during firing the elements 30 and 34 are capable of movement along with elements 12 and 12a as claimed within the

Art Unit: 3731

recess 43). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the lancet holding mechanism of the 841 application with the lancet holding mechanism as disclosed by Kuhr. Doing so would provide a means for automatically dispensing the lancet after use thereby reducing the risk of accidental needle puncture as taught by Kuhr note paragraph 12 of Kuhr.

Regarding claims 2-16, the 841 application and Kuhr as applied to claim 1 above discloses at least either of the first and the second members applies a pressing force to the lancet for fixing the lancet (note contact between lancet main body 4 and first member as depicted in fig. 2 further note paragraph 30), when loading the lancet, the lancet moves relative to the first member (note in figure 2 and 3 and note element 12a relative to lancet main body 4 in order to insert the lancet within the grasp of element 12a it would inherently have to move relative to it note reverse progression of fig. 3 to fig. 2 and further note paragraph 41), while the second member moves together with the lancet relative to the first member in the retreating direction from the non-fixing position toward the fixing position (paragraph 41), and wherein the lancet holder applies a greater pressing force to the lancet when the second member is located at the fixing position than when the second member is at the non-fixing position (note fixing force applied to element 3 by element 12a as depicted in figure 2 when the second element 30 is in the retracted state as depicted in figure 2), fixing means (element 30 which abuts the proximal end of element 4 and element 12a which surrounds element 4 and correspond with indentations 4a as depicted in fig. 2) that applies a pressing force to the lancet for fixing the lancet when the second member is at the fixing position (note fig. 2

Art Unit: 3731

and further note paragraph 30), the first and the second members respectively include a first engaging portion (portions of element 12a which correspond with element 4a of main body 4) and a second engaging portion (distal end of element 30 which abuts the proximal end of element 4 note fig. 2) that are engaged with each other when the second member is at the fixing position (note contact between elements 30 and 12, 12a as depicted in figure 4), the fixing means comprising the first and second engaging portions (note fig. 2), at least one of the first and the second engaging portions projects toward the other of the first and the second engaging portions (note the distal end of element 30 projects toward the distal end of element 12a as depicted in fig. 2), one of the first and the second engaging portions comprises a recess (portion of element 12a formed by the radially inward projecting distal ends creating a recess between the leg portion and radially inward projecting portion of element 12a as depicted in fig. 3), and the other of the first and the second engaging portions comprises a projection (distal end of element 30) to be fitted into the recess (note position of the distal end of element 30 relative to the aforementioned recess depicted in figure 3), the first member includes a pressing portion (projections of element 12a) that applies a pressing force to the lancet (note paragraph 30) and wherein the second member includes a working portion (distal surface of element 30) that displaces at least a part of the pressing portion from the lancet when the second member is located at the non-fixing position or between the non-fixing position and the fixing position (note progression of figures 2-3), the pressing portion includes a pair of movable portions (note the pressing portions are attached to the tongs 12a which move/deflect in order to release the lancet), wherein a gap is

Art Unit: 3731

provided between the pair of movable portions for allowing the working portion to move (note the progression figures 2-3 where the working portion projects distally between the movable portions of element 12a), and wherein the gap is expanded when the working portion moves through the gap, so that at least a part of the movable portions is displaced so as to separate from the lancet (note when element 12a deflects to release the lancet the distance between the tongues' of 12a must increase in order to release the lancet which is driven by the distal end of element 30), at least one of the movable portions includes at least one cutaway (portioned defined by the radially inward projecting projection of element 12a and the elongate portion of 12a which encompasses element 30 as depicted in fig. 3) that defines a part of the gap (note the cutaway as previously described defines a portion of the gap see also fig. 3), and that the working portion fits into (note aforementioned explanation and fig. 3), at least one cutaway comprises a first cutaway portion into which the working portion is fitted in fixing the lancet (note position of element 30 relative to the cutaway as defined above as depicted in fig. 2), and a second cutaway portion into which the working portion is fitted in discharging the lancet (note position of element 30 relative to the cutaway as defined above as depicted in fig. 3), at least one cutaway comprises a cutaway portion arranged to make the gap continuously or incrementally narrower when the working portion relatively moves with respect to the first member in the lancing direction (note in fig. 3 the cutaway as defined above comprises the radially inward projection portions of element 12a which taper in the lancing direction thus narrowing the gap between elements 12a), wherein the cutaway portion includes a tapered portion (note tapered

Art Unit: 3731

portion distal the radially inward most point of the radially inward projecting portions of element 12a) that makes the gap wider continuously as proceeding in the lancing direction (note figure 3), the cutaway portion includes a tapered portion that makes the gap wider continuously as proceeding in the lancing direction (note tapered portion depicted in figure 3 distal the radially inward most point of the radially inward projecting portions of element 12a) but fails to explicitly disclose wherein the cutaway portion includes at least one stepped portion that makes the gap wider sequentially as proceeding in the lancing direction. It would have been obvious to one skilled in the art at the time the invention was made to construct the tapered portion as disclosed by Kuhr with a series of stepped portions, since applicant has not disclosed that such a change in shape or form solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a tapered portion of a cutaway portion that makes the gap wider sequentially as proceeding in the lancing direction and it appears that the tapered portion of Kuhr would perform equally as well for the purpose of providing a tapered portion that makes the gap wider sequentially as proceeding in the lancing direction, the pressing portion includes a fixed portion (protruded portion of element 12a fixed to element 12a) and a movable portion (portions of 12a which deflect in order to release the lancet as depicted in the progression of figures 2-3), wherein a gap (space between the diametrically opposing portions of element 12a) is provided between the fixed portion and the movable portion for allowing the working portion to move (note figure 3), and wherein the gap is expanded when the working portion moves through the gap, so

Art Unit: 3731

that at least a part of the movable portions is displaced so as to separate from the lancet (note progression of figures 2-3 where the moveable portions of 12a allow deflection of 12a releasing the lancet when the distal end of element 30 is moved in a distal direction note also paragraph 30 and 34).

Regarding claims 17-18, the 841 application and Kuhr disclose, as applied to claim 1 above, a lancet moving mechanism for moving a lancet (note discussion with regard to claim 1 above) and with regard to the Kuhr reference a lancing apparatus (1) comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (30) and a second member (12a) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by second member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet

Art Unit: 3731

main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder, the second member (capable of) being moved in the lancing direction together with the first member and the lancet when the second member is held in the fixing position for fixing the lancet to the lancet holder (note that during the loaded primed configuration, as depicted in figures 8 and 2, and during firing, portion 34 of element 30, note figures 4 and 5, is capable of moving in a puncture direction 7 within recess 43 note paragraph 36, therefore during firing the elements 30 and 34 are capable of movement along with elements 12 and 12a as claimed within the recess 43), wherein the second member (as disclosed above) includes a pair of movable portions (deflection portions of 12a) for holding the lancet there between (note figure 2), and wherein the movable portions are displaced away from the lancet when the second member is relatively moved with respect to the first member in the lancing direction (when the aforementioned first member moves in a distal direction elements 12a must deflect/move in order to release lancet 3 from there grasp note progression of figures 2-3), but displaced toward the lancet when the second member is relatively moved with respect to the first member in the retreating direction (note in paragraph 30 and 41 when the aforementioned first member is retracted by insertion of the lancet the second member moves relative to the first member toward the lancet in order to engage the recesses 4a within lancet 3 note figure 2), wherein the lancet comprises a recess (4a), and wherein the movable portion comprises an engaging portion (radially inwardly portions of element 4a) to be engaged with the recess (note figure 2).

Regarding claims 19-20, the 841 application and Kuhr disclose, as applied to claim 1 above, a lancet moving mechanism for moving a lancet (note discussion with regard to claim 1 above) and with regard to the Kuhr reference a lancing apparatus (1) comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (12a) and a second member (proximal end of element 4) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 2) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by first member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder (note paragraph 39), the second member (capable of) being moved in the lancing direction together with the first member and the lancet when the second member is held in the

Art Unit: 3731

fixing position for fixing the lancet to the lancet holder, and a pushing member (32) that moves the second member in the lancing direction (paragraph 43), wherein the pushing member (30) includes a working portion (distal ends of 31) that interferes with the second member (note in fig. 2 and 4-5 where the working portion abuts and thus interferes with the second member) and an operating portion (30) to be manipulated so as to move the working portion (paragraph 43).

Regarding claim 21, the 841 application and Kuhr disclose, as applied to claim 1 above, a lancet moving mechanism for moving a lancet (note discussion with regard to claim 1 above) and with regard to the Kuhr reference a lancing apparatus comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction, thus to be retained by the lancet holder (paragraph 41), wherein the lancet holder includes a first member (30) and a second member (12a) that are movable relative to each other in a needle extending direction (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder and a non-fixing position (as depicted in figure 3) in which the main body of the lancet is allowed to be removed from the lancet holder, the second member including a movable fixing portion (protrusions at the distal end of

Art Unit: 3731

element 12a that correspond with recess 4a in the lancet body) that moves in a direction crossing the needle extending direction (radially outward note progression of fig. 2-3 and paragraph 30) for fixing contact with the main body of the lancet in response to the movement of the second member from the non-fixing position to the fixing position (as depicted in the progression of figures 2-3 and 7-9), the second member (capable of) being moved in the lancing direction together with the first member and the lancet when the second member is held in the fixing position for fixing the lancet to the lancet holder (note that during the loaded primed configuration, as depicted in figures 8 and 2, and during firing, portion 34 of element 30, note figures 4 and 5, is capable of moving in a puncture direction 7 within recess 43 note paragraph 36, therefore during firing the elements 30 and 34 are capable of movement along with elements 12 and 12a as claimed within the recess 43).

This is a provisional obviousness-type double patenting rejection.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 3731

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Eastwood whose telephone number is (571)270-7135. The examiner can normally be reached on Monday through Friday from 9 a.m. – 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. E./
Examiner, Art Unit 3731
10/6/11

/S. Thomas Hughes/
Supervisory Patent Examiner, Art Unit 3731